DEVELOPMENT OF EVIDENCE-BASED TOOLS FOR DELIVERY OF MEDICATION-ASSISTED TREATMENT IN OPIOID DEPENDENCY

By

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A Project Submitted in Partial Fulfillment of the Requirements

for the Degree of

MASTER OF SCIENCE

in

Nursing Science

University of Alaska Anchorage

May 2017

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Abstract

Opioid use and resultant deaths have been declared an epidemic. The purpose of this project was to develop an outpatient primary care evidence-based toolkit for medication-assisted treatment (MAT) in opioid dependence for Alaska nurse practitioners (NPs). The focus was to enhance provider knowledge of MAT modalities and to facilitate practice implementation with an overall goal of increasing knowledgeable health professionals thereby increasing patient access to treatment. The Plan, Do, Study, Act framework was used to implement an educational presentation of current MAT modalities and to develop the MAT toolkit as previously mentioned. A post-implementation survey was used to evaluate the project outcomes. The data obtained from the questionnaire demonstrated participant knowledge of MAT modalities with the intent to provide MAT and to use the toolkit in future clinical practice.

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Development of Evidence-Based Tools for Delivery of Medication-Assisted Treatment in Opioid Dependency

Opioid dependency has been a growing health concern globally and nationwide. World Health Organization (WHO, 2014) reported an estimated 15 million people worldwide were addicted to opioids, including both heroin and prescription opioids. Of that 15 million, the United States (US) accounts for just over two million opioid addicts. Drug overdose in the US is now the leading cause of accidental death (American Society of Addiction Medicine [ASAM], 2016). In 2012, the overdose deaths related to opioid pain relievers in Alaska were more than double the national rate ("SOA Epidemiology," 2016).

In 2015, opioid pain relievers and heroin accounted for more than 80% of the total drug overdose deaths in the state of Alaska. From less than five deaths in 2010 to 34 in 2015, this ten-fold increase of opioid overdose deaths illustrates the significance of the opioid epidemic present in our state ("State of Alaska Epidemiology," 2016). While there have been effective treatments for opioid dependence, only 10% of people who needed treatment were receiving care (WHO, 2014). In 2012, 14,000 of the 19,000 illicit drug users in Alaska felt they needed substance abuse treatment; however, a single day count for individuals enrolled in a substance abuse treatment program in Alaska for 2012 was 3,658. Of these enrollees, only 168 were in an opioid treatment program (SAMHSA, 2015b).

Problem and Topic Overview

One particular measure in addressing the opioid epidemic was to increase the availability of opioid dependence treatment (Volkow, Frieden, Hyde, & Cha, 2014; WHO, 2014). Guidelines for treatment have been a combination of psychosocial interventions and MAT (Kampman & Jarvis, 2015). The three Federal Drug Administration (FDA) approved MAT

options include methadone, buprenorphine, and naltrexone (ASAM, 2015; SAMHSA, 2016a). Opioid use and resultant deaths have been declared an epidemic with suboptimal treatment as a likely contributor; inadequate access to treatment due to the limited amount of providers who were willing or able to provide these treatments is a form of suboptimal treatment (Kampman & Jarvis, 2015).

A variety of care settings can be used to deliver opioid dependence treatment, such as residential or hospital opioid treatment facilities (OTP), and office-based or outpatient opioid treatment programs (OBOT). Though three MAT options are available, the utilization of these medications for opioid dependency has not been widely available. In 2012, of the 2.5 million opioid dependent Americans age 12 or older, less than 1 million received MAT (SAMHSA, 2013).

Nearly half of the patients seen by primary care providers report some issue related to substance use or abuse, indicating that initiation of treatment often begins in the primary care setting (SAMHSA, 2015a). When opioids travel through the bloodstream, they attach to mu opioid receptors in the brain and activate the reward system, which gives off a feeling of pleasure. When opioids activate the reward system in the absence of significant pain, they can motivate repeated use of opioids to maintain that sense of pleasure and lead to opioid misuse or abuse, tolerance, and dependence (Kosten & George, 2002). Repeated exposure to escalating opioid dosages can produce abnormal brain functioning when the drugs are both present and when they are not. The results of these brain alterations are opioid tolerance (the need to take increasingly higher doses of opioids to achieve the same opioid effects) and opioid dependence (the susceptibility to withdrawal symptoms in the absence of opioids after tolerance has occurred) (Kosten & George, 2002). Like other chronic diseases such as diabetes, asthma, and

hypertension, the management of opioid dependence should be approached with evidence-based treatments immediately available to prevent the loss of opportunity to treat (ASAM, 2015; National Institute on Drug Abuse [NIDA], 2014). With a vast majority of Nurse Practitioners (NP) holding family practice certifications, there is an opportunity for family NPs to decrease the gap in treatment availability by providing outpatient MAT (American Association of Nurse Practitioners [AANP], 2016).

Significance

The opioid drug class includes the street drug heroin, in addition to, prescription medications such as oxycodone, hydrocodone, codeine, morphine, and fentanyl. Routine use of opioids can lead to dependence or abuse and can result in overdose and death (NIDA, 2014). In 2012, approximately 335,000 persons ages 12 years or older in the US reported current heroin use and 4.9 million reported the current use of nonmedical pain relievers (SAMHSA, 2013). In that same period, 23,000 Alaskans ages 18 years or older reported use of nonmedical pain relievers in the past year and 19,000 people ages 18 years or older who reported current use of illicit drugs other than marijuana (SAMHSA, 2016b). The significant amount of opioid dependent individuals presents both health and financial concerns for Alaska and the nation.

Societal Impact

In 2007, the total economic burden of prescription opioid dependency equaled $55.7 billion dollars; three categories included in this cost were workplace, healthcare, and criminal justice costs (Birnbaum, White, Schiller, Waldman, Cleveland, & Roland, 2011). Lost workplace productivity accounted for $25.6 billion of the deficit, health care costs was $25.0 billion, and the remaining $5.1 billion came from criminal justice costs (Birnbaum et al., 2011).

This tremendous economic burden has been a result of the multidimensional consequences due to the complexity of the disorder.

Opioid dependence can involve every aspect of an individual's functioning; personality and behavior changes of opioid abuse can have negative consequences which can manifest symptoms in marriage or relationships, home and family life, education, employment, health, personality, finances, and law and order (NIDA, 2012). These negative consequences reach beyond the affected individual. Hardship within families can arise due to misunderstandings of the disease process or the person's behavior due to drug use, draining of family resources, illness or death as a result of substance abuse, distortion of interpersonal family relationships, and violence (NIDA, 2009).

Health care consequences of opioid use disorder may include but are not limited to hepatitis C virus (HCV) infection, human immunodeficiency virus (HIV), psychiatric illnesses, and overdose or death (NIDA, 2014). In 2010, the total hospital costs for drug abuse-related illness in Alaska was $12.9 million (Alaska Advisory Board on Alcoholism and Drug Abuse, McDowell Group, Inc. [AABADA], 2012). These health consequences have a negative impact on the individual, the health care system, and families that provide financial and emotional support.

Chronic opioid abuse has been shown to cause long-lasting changes in the brain that has contributed to the individual's compulsion to seek and use drugs despite the catastrophic consequences (NIDA, 2014). Incarcerations and entering the criminal justice system have been included within these consequences. The link continues between substance abuse and criminality as individuals often turn to crime as a means to supporting their addiction. In 2010,

there were 18,296 arrests in Alaska that were related to substance abuse with 1,529 resulting in incarcerations at the cost of $56.7 million (AABADA, 2012).

Though effective treatments for opioid dependence exist, only 10% of people who have needed treatment were receiving it (WHO, 2014). In Alaska, 14,000 of the 19,000, illicit drug users reported needing treatment but were not receiving it; this equated to only 27% of the opioid-dependent individuals receiving the medical care required for their chemical dependence (SAMHSA, 2016b). Further investigation of treatment rates showed a single day count for people enrolled in substance abuse treatment in Alaska was 3,658 during 2012; of these enrollees, only 168 were in an opioid treatment program (SAMHSA, 2015b). This shows a vast disparity in the number of individuals needing treatment and those who are receiving it.

Increasing access and availability of MAT are essential components of a comprehensive response to the opioid epidemic and could decrease the significant and widespread impacts of this disease (NIDA, 2012; Volkow et al., 2014). Family practice NPs in Alaska can increase access to treatment by providing MAT in the outpatient setting, as they are well-trained providers in health promotion and disease prevention. The scope of practice of NPs includes the assessment, diagnosis, treatment, and management of illness (AANP, 2015). Opioid abuse is a chronic disease that NPs can diagnose and treat by preventing relapse and adverse effects, which include death, long-term health consequences, adverse effects on relationships, employment issues or job loss, legal problems or incarceration, and psychological problems (ASAM, 2013; Birnbaum et al., 2011). The underutilization of MAT in the primary care setting has created an opportunity for NPs to decrease the gap in treatment access and availability.

Practice Improvement Question

Clinical inquiry questions are often designed using the PICOT format. Utilizing the PICOT method facilitates the development of a concise question to address proposed solutions of an observed problem. The PICOT question includes a patient population of interest (P), intervention or area of interest (I), comparison intervention or group (C), outcome (O), and time (T) (Melnyk, Fineout-Overholt, Stillwell, & Williamson, 2010).

(P) The population encompasses licensed family nurse practitioners (NP) within Alaska working in outpatient primary care.

(I) The interventions include education of MAT modalities within the scope of practice for Alaska NPs and implementation of an evidence-based toolkit providing guidelines/protocols and information necessary for the implementation of MAT into clinical practice.

(C) There is no comparison.

(O) Increase provider understanding of MAT options, satisfaction with training, and utility or intent to use the MAT toolkit.

(T) The timeline is as follows: education and evidence-based toolkit implementation in a primary care setting with post-implementation survey data collection on the same day.

Research Question

Does education of MAT modalities and the implementation of an evidence-based toolkit increase understanding of MAT options and facilitate the utilization of MAT by Alaska family nurse practitioners working in primary care?

Purpose

The purpose of this practice improvement project was to develop an outpatient primary care evidence-based toolkit for MAT in opioid dependence for Alaska nurse practitioners. The

project aimed to enhance provider knowledge of MAT modalities and to facilitate practice implementation with an overall goal of increasing the availability of trained and knowledgeable health professionals thereby increasing patient access to treatment for opioid dependency.

Literature Review

Current practice recommendations indicate opioid dependence is a chronic illness to be treated with a combination of psychosocial and pharmacotherapy (ASAM, 2015; National Guideline Clearinghouse [NGC], 2011). Three pharmacological treatments approved by the federal drug administration (FDA) for opioid dependency are methadone, buprenorphine, and naltrexone (ASAM, 2015; SAMHSA, 2016a). The choice of medication used for treatment is multifactorial; providers must consider key features of all modalities.

Medication-Assisted Treatment Options

Methadone. This drug is a long-acting synthetic opioid agonist, which activate opioid receptors (SAMHSA, 2016a; U.S. Department of Justice Drug Enforcement Administration [U.S. DOJ DEA], 2006). It is used to suppress opioid withdrawal, block the effects of illicit opioids, reduce opioid cravings, and reduce or stop the use of illicit opioid. It is taken orally and can be used as a long-term maintenance medication to prevent relapse (ASAM, 2015; NGC, 2011; NIDA, 2012; SAMHSA, 2016a). Methadone is also associated with physiologic dependence and has a risk of diversion, abuse, and overdose if drug dosing is not carefully monitored; it may only be prescribed by a physician and dispensed within a SAMHSA-certified Opioid Treatment Program (OTP) (ASAM, 2015; NIDA, 2012; SAMHSA, 2016a).

Buprenorphine. This drug is a synthetic partial opioid agonist, which also activates opioid receptors, but has a smaller response (SAMHSA, 2016a; U.S. DOJ DEA, 2006). It is also used to suppress opioid withdrawal, block the effects of illicit opioids, reduce opioid cravings,

and reduce or stop the use of opioids (ASAM, 2015; NGC, 2011; NIDA, 2012; SAMHSA, 2016a). Like methadone, buprenorphine is taken orally and can be used as a long-term maintenance medication to prevent relapse; it also carries a risk of physiological dependence, though less severe than that of methadone (ASAM, 2015; NIDA, 2012; SAMHSA, 2016a). Buprenorphine can only be prescribed by providers, including NPs, with board certification in addiction medicine or addiction psychiatry or have completed specialized training to qualify for the federal waiver required for prescriptive authority (NIDA, 2014; U.S. DOJ DEA, 2006).

Naltrexone. This drug is a synthetic opioid antagonist that blocks opioids from binding to receptor sites to prevent the euphoria and reward response effect caused by opioids (ASAM, 2015; NIDA, 2012; SAMHSA, 2016a). It is supplied as both an oral (taken daily) and injectable (taken monthly) medication and is used to block the effects of illicit opioids and reduce opioid cravings, and reduce or stop the use of opioids (ASAM, 2015; NIDA, 2012; SAMHSA, 2016a). Unlike methadone and buprenorphine, naltrexone is not indicated for opioid withdrawal, does not carry the potential for abuse or diversion, and does not require special certification or waivers for prescription (ASAM, 2015; NIDA, 2012; SAMHSA, 2016a; U.S. DOJ DEA, 2006). The injectable form of naltrexone is referred to as XR-NTX.

Guidelines for Treatment

To assist in the evaluation and treatment of opioid use disorders, the ASAM released The National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use (2015). The guideline is composed of scientific evidence and clinical knowledge from 34 previous guidelines that address the use of medications and psychosocial treatments for opioid use disorders. The existing 34 guidelines were based on systematic reviews of the

literature and offer the highest level of evidence-based recommendations included in the new ASAM guideline (ASAM, 2015).

Current practice guidelines have recommended treatment of opioid use disorders to include a combination of withdrawal management and psychosocial therapy or psychosocial therapy combined with methadone, buprenorphine, or naltrexone (ASAM, 2015). Aside from methadone and buprenorphine, the alpha2-adrenergic agonist clonidine has also shown to be an effective treatment for opioid withdrawal management (Gowing, Farrell, Ali, & White, 2016). While a recent systematic review of the literature found that clonidine was more effective than placebo in the management of opioid withdrawal, it is not approved by the FDA for this indication (Gowing et al., 2016; ASAM, 2015). As such, withdrawal management will not be discussed in depth, as NP general prescriptive authority for MAT is limited to naltrexone. Caution should be taken to prevent severe withdrawal symptoms caused by naltrexone; use only after detoxification and when the individual is no longer physically dependent on opioids (ASAM, 2015; NIDA, 2012; SAMHSA, 2016a).

Opioid Withdrawal Treatment Assessment

The first step to providing MAT is the assessment and diagnosis of opioid use disorder to determine the need for treatment (ASAM, 2015; SAMHSA, 2016a). This step includes measuring the severity of substance use disorder and withdrawal, identifying co-occurring diseases or conditions, evaluating the effect of the opioid use on physical and psychological function, determining outcomes of previous treatment, and obtaining the patients' medical and behavioral health history (ASAM, 2015; SAMHSA, 2016a). If the patient is experiencing moderate to severe withdrawal, inpatient treatment referral may be necessary for medically managed withdrawal from opioids (ASAM, 2015; NIDA, 2012; SAMHSA, 2016a).

After establishing the diagnosis of substance use disorder, the choice of medication treatment should be a shared decision between the patient and provider (ASAM, 2015; SAMHSA, 2016a). Patient education about the risks and benefits of all medication options are reviewed, including relapse and overdose prevention. Referral to a higher level of care can also be made at this time if treatment with XR-NTX is not appropriate (ASAM, 2015; NIDA, 2012; SAMHSA, 2016a).

Medication-Assisted Treatment

While the use of methadone and buprenorphine has long been established in the treatment of opioid abuse, prescribing these medications may be somewhat limited due to federal regulations (ASAM, 2015; NGC, 2011). As previously stated, methadone may only be prescribed or dispensed by a SAMHSA-certified OTP and buprenorphine by providers who meet requirements for its prescriptive authority (NIDA, 2014; SAMHSA, 2015a; U.S. DOJ DEA, 2006). Practitioner limitations of these medications contribute to the limited access and availability of MAT both nationwide and within the state of Alaska.

For individuals living in areas where methadone and buprenorphine are unavailable, for those who are highly motivated and want to taper off their current agonist therapy, or persons not wanting treatment with an opioid agonist use of XR-NTX should be considered (ASAM, 2015; NIDA, 2012; SAMHSA, 2016a). If the patient is medically and psychologically stable and XR-NTX deemed appropriate, the provider and patient then develops a comprehensive, individualized treatment plan; this includes integration of counseling and other psychosocial therapies, social support and mutual help programs with pharmacological treatment (ASAM, 2015; NIDA, 2012; SAMHSA, 2016a). In compliance with the state of Alaska nursing statutes, Drug Enforcement Agency (DEA) policies, and national practice guidelines, the only MAT

option available to NPs that does not require special licensing, certification, or waivers is XR-NTX (State of Alaska Board of Nursing [SOA BON], 2014; U.S. DOJ DEA, 2006). While no single treatment is appropriate for everyone, XR-NTX can be useful when methadone and buprenorphine are unavailable or inaccessible (ASAM, 2015; NIDA, 2012; SAMHSA, 2015a, SAMHSA, 2016a). The FDA approved the injectable release naltrexone (XR-NTX) for the treatment of alcohol dependence in 2006 and 2010 for the treatment of opioid dependency (Alanis-Hirsch et al., 2015). In comparison to receiving no MAT for opioid dependence, XR-NTX has been indicated to be safe and efficacious.

In 2011, a double-blind placebo-controlled randomized trial was conducted to assess the efficacy, safety, and patient-reported outcomes of once-monthly dose XR-NTX in the treatment of opioid dependency (Krupitsky, Nunes, Ling, Illeperuma, Gastfriend, & Silverman, 2011). The 24-week trial included opioid dependent individuals ages 18 years and older across 13 treatment sites in Russia; after randomization to XR-NTX (n = 126) or placebo (n = 124) groups, analyses of the primary endpoint of abstinence of opioids during weeks 5-24 was 90.0% (95% CI = 69.9, 92.4) in the XR-NTX group and 35.0% (11.4, 63.8) in the placebo group (PBO) ($p < .01$). Analyses of secondary endpoints were self-reported opioid-free days, opioid craving scores, the number of days in retention, and relapse to physiological opioid dependence; all endpoints resulted in statistically significant differences ($p < .01$) indicating the superiority of XR-NTX treatment over placebo (Krupitsky et al., 2011).

The result of this study was pivotal in the approval of XR-NTX for opioid dependence in the US as it provided significant information in the use and efficacy of XR-NTX as an alternative pharmacotherapy in the treatment of opioid dependence (Syed & Keating, 2013). The study demonstrated that opioid-dependent adults voluntarily seeking treatment who received XR-NTX

when compared to those who received placebo had a higher treatment retention rate, more opioid-free weeks, fewer relapses to physiological opioid dependence, and greater reductions in opioid cravings (Krupitsky et al., 2011).

Following the six-month trial, there was a 52-week open-label extension phase that continued to measure the long-term safety and effectiveness of XR-NTX (Krupitsky, Nunes, Ling, Gastfriend, Memisoglu, & Silverman, 2013). During the extension phase (n = 114), 67 XR-NTX patients continued with monthly injections, and 47 patients transitioned from PBO to receive XR-NTX. 62.3% (95% CI = 52.7, 71.2) of the participants completed the trial; primary reasons for discontinuation was the withdrawal of consent (18.4%) and loss to follow-up (11.4%) (Krupitsky et al., 2013). Overall, 50.9% (95% CI = 41.5, 60.4) were abstinent from opioids, 21.1% of patients reported adverse events, 6.1% experienced injection site reactions, and 16.7% had elevations in liver function (Krupitsky et al., 2013). Participants with elevated liver enzymes were equally from the original group of XR-NTX participants, and PBO to XR-NTX and serum elevations were clinically judged as non-significant (Krupitsky et al., 2013). The study identified no new safety concerns were identified, and long-term treatment with XR-NTX showed encouraging rates of retention and opioid abstinence, low rate of adverse events, no severe adverse events, and a low overall rate of injection site pain (Krupitsky et al., 2013).

Comparison of MAT options to determine the superiority of one drug over the other is difficult due to the lack of evidence-based literature. Systematic long-term studies of MAT have been rare, and comparison of treatment retention rates has been difficult due to the varying study designs and characteristics (Krupitsky, 2013; Syed & Keating, 2013). To date, there have been no published clinical trials directly comparing the efficacy and safety of XR-NTX with methadone or buprenorphine in the treatment of opioid dependency (Syed & Keating, 2013).

Outpatient Treatment

Access to MAT with methadone and buprenorphine treatment has been limited in part due to the small number of qualified prescribing providers. It has been currently estimated that only two OTP facilities and 19 buprenorphine-certified physicians have been available in the state (Opiate Addiction and Treatment Resource, n.d.). The issue of a limited number of buprenorphine-certified providers was further compounded by the fact that each prescriber may only treat a maximum of 30 to 100 patients at any given time (U.S. DOJ DEA, 2006). Increasing the number of outpatient primary care providers who were knowledgeable and able to provide outpatient MAT could increase treatment availability (Volkow et al., 2014).

Recently, a web-based survey study was conducted to estimate the demand for primary care-based treatment for substance and alcohol use disorders. The 344 study participants with substance use disorder were randomly assigned to one of three treatment conditions (usual care, primary care, or collaborative care) to determine their willingness to enter treatment based on the characteristics of the treatment alone (Barry, Epstein, Fielin, Fraenkel, & Busch, 2016). The description of usual care included treatment in a specialty drug treatment center with ongoing counseling, medication, or both. Primary care included the same treatment as usual care, but in an office setting with the added benefits of receiving care for other medical issues and the option of a referral to addiction specialty for more intensive treatment. Collaborative care was also described as office based with the same treatment as primary care but included further benefits of treatment coordination, additional counseling, referrals, crisis management, and other services from a nurse case manager (Barry et al., 2016). All treatment vignettes were also described to participants as having no out-of-pocket costs and being available in their area with open appointments (Barry et al., 2016).

Results of participants who were willing to enter treatment (n = 107) were 24.6% from the usual care group, 37.2% from the primary care group (12.6 percentage point difference; 95% CI = .8, 24.4), and 34.0% from the collaborative care group (9.4 percentage point difference; 95% CI = -2.0, 20.8); willingness to enter treatment was comparable between the primary care and collaborative care groups (3.2 percentage point difference, 95% CI = -9.8, 16.3) (Barry et al., 2016). Among participants who were not willing to enter treatment (n = 237), the most common reason reported was the belief that treatment was not needed (63%); there was no significant difference among the three groups (p = .48).

The results of this study concluded that participants with a substance use disorder were more willing to enter primary care-based treatment versus usual care in a specialty drug treatment facility (Barry et al., 2016). Though encouraging, the results of this study were not generalizable to the entire population of substance use disorder as participants were limited to include only individuals with no prior treatment experience (Barry et al., 2016). Previous experience with treatment was important to consider as it may affect the individual's beliefs about the effectiveness and desirability of different treatment settings (Barry et al., 2016). Another limitation of the study was the treatment vignette did not explicitly describe the setting of the specialty drug treatment center. It was not made clear that the specialty drug treatment was provided in an outpatient treatment center, not a residential facility, which could have produced varying results (Barry et al., 2016). Despite the limitations, the study indicates that broader availability of primary care-based treatment options may be useful in increasing treatment rates (Barry et al., 2016).

Nurse Practitioner Role

Opioid dependency should be approached as any chronic disorder, requiring continuing care throughout the lifespan. Successful treatment is dependent on adherence to medications and behavioral changes, which are designed to increase functional status, quality of life, life expectancy, and to reduce factors for recurrence of the disorder. Multiple quality and effectiveness of care outcome comparison studies have identified no significant differences in patient care outcomes between NPs and physicians in the provision of general care for chronic illnesses (Stanik-Hutt et al., 2013). NP roles in health, healthcare prevention, and outcome improvement have been continually evolving and expanding. The provision of naltrexone for opioid dependency in the family practice setting has been encompassed in that role as a result of the opioid epidemic and recommendations for early identification and treatment of the disease (AANP, 2015; ASAM, 2013).

In searching the SAMHSA, DOJ DEA, State of Alaska, and other websites, was unclear of the exact number of MAT providers who were truly available in Alaska. According to the Opiate Addiction and Treatment Resource website, there were 19 physicians certified to prescribe buprenorphine in the Anchorage/Mat-Su area; however, this information was last updated in January 2014 (Opiate Addiction and Treatment Resource, n.d.). The site also listed one OTP in Anchorage and one in Fairbanks; again, the accuracy of this information was unclear as it was last updated in October of 2013 (Opiate Addiction and Treatment Resource, n.d.). The limited number of MAT providers currently available compared to the most recent number of opioid abusers suggested the need for increased community access to MAT.

Methods

Conceptual Framework

The plan, do, study, act (PDSA) is a model that provides a framework for developing, testing, and implementing changes leading to quality improvement of care (Agency for Healthcare Research and Quality [AHRQ], 2015). The PDSA cycle was utilized to provide the framework for implementation of an evidence-based toolkit that included guidelines, protocols, or information necessary for the provision of XR-NTX in an outpatient family practice setting. The goal of the PDSA cycle application was to determine if the MAT toolkit would increase provider knowledge of available MAT options for opioid dependence and if it would facilitate the adoption of MAT into clinical practice.

The four stages of the PDSA cycle are plan, do, study, and act. In the planning stage, the primary investigator identifies the change to be tested or implemented and a method for data collection. The second stage, the do phase, consists of carrying out the plan in step one. The next stage is the study period, which is the analysis of the data and summarization of what is learned. The final stage of the PDSA cycle is act. In the act stage, implementation revisions are made and the planning of the next PDSA cycle occurs.

Plan. The initial step of the Planning stage was to identify the topic and problem for this quality improvement project. After reviewing current guidelines and evaluating the literature, the project objectives, goals, and timeline were determined. This step also involved developing an educational presentation for primary care opioid dependence treatment using XR-NTX by nurse practitioners, the development of a post-implementation questionnaire to assess knowledge of MAT therapy, and assembling supportive clinical tools that would promote practitioner comfort and safe use of XR-NTX. The owner of an outpatient family practice clinic expressed

interest in the project topic and provided project implementation support; four of the five providers employed in the center voluntarily participated in this project.

Do. The second stage of PDSA is the Do phase, which was completed on April 8, 2017. This stage encompassed three parts:

1. Delivering an educational presentation as the implementation part of this project (see Appendix B).
2. Dissemination of the MAT Toolkit (see Appendix C).
3. Survey evaluation of the presentation and MAT Toolkit (see Appendix D). All participants were expected to complete the questionnaire after the presentation of the information.

Study. The third stage, or Study phase, included analyzing the post-implementation survey data for provider knowledge of MAT therapy after education, intent to provide MAT and the future use of the toolkit, and recommended areas of improvement of the clinical toolkit. The collected survey results included ordinal data from the Likert scale questions, data from multiple choice questions, and feedback from the open-ended question. The questionnaire results were evaluated and analyzed for measures of central tendency. Provider knowledge, intent to provide MAT and utilization of the toolkit, and kit improvement suggestions are reported using descriptive statistics and frequency distributions.

Act. The final stage, or "Act" phase, involved performing revisions to the MAT toolkit as suggested by project participants before the redistribution and dissemination of the materials. The revised toolkit will be disseminated to the pilot clinic and will be made available on the Alaska Nurse Practitioner Association (ANPA) website. A poster presentation at the 2017 ANPA conference will be available.

Rights of Human Subjects

Agreement and support from the pilot clinic administration were obtained before the project implementation. The project was submitted and approved by the UAA IRB as not human subject research (see Appendix A). The project did not contain human subjects and participation was voluntary. Education and training were provided along with a post-implementation survey; the survey information was de-identified and used only to evaluate the project improvement goals.

Results

The post-implementation survey was comprised of seven questions. Questions one through four were multiple choice, questions five and six were a 5-point Likert scale, and question 7 called for an open-ended response (see Appendix D). The questionnaire was completed by all four participants. The result of each question is listed and detailed separately in the following section.

Question 1: What are the three MAT medications approved by the Food and Drug Administration (FDA) for the treatment of opioid dependence?

One hundred percent (4 of 4) of the participants chose the correct answer of methadone, naltrexone, and buprenorphine.

Question 2: Special certifications or prescriptive authority (aside from a DEA license) are required for all three MAT medications**.**

One hundred percent (4 of 4) of the participants chose the correct answer of false.

Question 3: For some opioid dependent patients, MAT is not necessary once they are past the detoxification phase and have been opioid-free for at least 7 to 10 days.

One hundred percent (4 of 4) of the participants chose the correct answer of false.

Question 4: Treatment for opioid dependence should be approached like other chronic diseases such as diabetes, asthma, and hypertension.

Seventy-five percent (3 of 4) of the participants agreed. Twenty-five percent (1 of 4) of the participants neither agreed nor disagreed.

Question 5: How likely are you to provide medication-assisted treatment for opioid dependence after toolkit dissemination?

Fifty percent (2 of 4) of participants answered very likely. Fifty percent (2 of 4) responded somewhat likely.

Question 6: Do you intend to use the MAT toolkit in future practice?

Seventy-five percent (3 of 4) of the participants answered definitely. Twenty-five percent (1 of 4) participants answered most likely.

Question 7: Is there any information you feel would be helpful to include in the toolkit?

- A true pocket-sized "MAT of Opioid Use Disorder, Pocket Guide."
- A list of support group contacts, mental health counselors, and substance abuse counselors
- You included all of the major factors that I would need to be comfortable, except need more instructions on treatment of opioid withdrawal before MAT initiation
- A template for electronic medical record

Discussion and Conclusion

Implementation Barriers

The first obstacle encountered was the delay of University of Alaska Anchorage (UAA) Institutional Review Board (IRB) request for determination of human subject research. The initial application submission on January 16, 2017 resulted in a response received February 10,

2017 and determined the project to be human subject research. The revision of evaluation methods was required to focus on participant knowledge and recommendations for toolkit improvement versus the actual participants and their perceptions. Submission of a revised IRB application took place March 06, 2017 and immediate approval by the IRB compliance officer was received the same day indicating the project was not human subject research.

The next obstacle encountered was the gathering of all components necessary for the MAT toolkit. Permission to utilize copyrighted materials and ordering the materials took more time than anticipated. Time constraints also affected the ability to evaluate participant utilization of the MAT toolkit. The MAT modality education, toolkit dissemination, and post-implementation survey occurred on the same day due to the limited time available for project completion. Because of this time constraint, participant intent to provide MAT for opioid dependency and intent to use the toolkit in future clinical practice is based on the satisfaction of the information presented and not the clinical practicality; participants did not have the opportunity to utilize the materials in practice over four to six weeks as originally planned.

Project Limitations

Several limitations were identified during and after the completion of this quality improvement project. The sample size was small as only one outpatient primary clinic was used. The small non-probability convenience sampling limits the generalizability of the project findings. Time constraints prevented the use of the toolkit by participants over four to six weeks as originally planned, which could have provided data on actual provider implementation of the toolkit and not just intent to use. Also, a pre-education survey may have provided more accurate measures of provider knowledge before and after the MAT education presentation.

Outcomes

The two intended goals of this project were (1) to increase knowledge of MAT options for opioid dependence, and (2) to develop a MAT toolkit to facilitate utilization of MAT into clinical practice; both goals were partially met. The first four questions of the post-implementation survey measured knowledge; three questions were answered correctly by 100% of the participants, and one question was answered correctly by 75% of the participants. Questions five and six assessed provider intent to provide MAT after the toolkit dissemination and intent to use the toolkit in future clinical practice. All participants were somewhat likely or very likely to provide MAT and all participants most likely or definitely intended to use the toolkit in future practice. While the MAT toolkit assembled contained information providers felt necessary to facilitate MAT into clinical practice, there was no data measuring that they did indeed utilize the toolkit or implement MAT.

Overall, the education of MAT modalities and the toolkit for opioid dependence were well received by all participants. The intent to provide MAT for opioid dependency, their intent to utilize the MAT toolkit in future clinical practice; and 100% participant response and feedback from the open-ended question is encouraging for further studies. Further studies could provide data on actual toolkit use by providers and the comparison of MAT patients before and after toolkit implementation to assess increased access and availability. Future projects with a larger sample size could also identify other beneficial components to include in the toolkit and keep providers abreast of the most current evidence-based guidelines.

Significance for Advanced Nursing Practice

The development of an outpatient primary care evidence-based toolkit for MAT in opioid dependence for Alaska NPs can enhance awareness and knowledge of current MAT options. It

can also assist in the provision of safe, effective, evidence-based care, facilitate the implementation of MAT into clinical practice, and increase the number of NPs who can provide MAT. Increasing the number of providers who are knowledgeable and able to provide MAT for opioid dependent people can increase the access and availability of MAT, which could decrease the significant widespread impacts of this disease (NIDA, 2012; Volkow et al., 2014). Increasing the access and availability could offer positive outcomes to opioid dependent persons, their families, and the community.

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Appendix A

IRB Determination

From: **Sharilyn Mumaw** simumaw@alaska.edu
Subject: Re: Request for IRB determination form
Date: March 6, 2017 at 1:15 PM
To: Charlene Hill chill64@alaska.edu
Cc: Sharilyn I Mumaw simumaw@uaa.alaska.edu, Lisa Jackson lmjackson2@alaska.edu

SM

Charlene,
Here is your copy of your determination of not HSR.
Regards,
Sharilyn

On Mon, Mar 6, 2017 at 7:01 AM, Charlene Hill <chill64@alaska.edu> wrote:

> Good morning Sharilyn,
>
> Please find attached is a revised/updated IRB determination form for my project.
>
> ~Charlene Hill
>
> > On Jan 16, 2017, at 3:18 PM, Charlene Hill <chill64@alaska.edu> wrote:
> >
> > <Hill_Request for IRB Determination.pdf>

--
***Sharilyn Mumaw**, M.P.A.*
Research Integrity and Compliance Officer
Research and Graduate Studies | University of Alaska Anchorage
3211 Providence Drive | BOC-3 376 | Anchorage, Alaska 99508
simumaw@uaa.alaska.edu | 907-786-1099

SoN - Hill - ND 696
Opiod Depe…t HSR.pdf

UAA UNIVERSITY of ALASKA ANCHORAGE

INSTITUTIONAL REVIEW BOARD
REQUEST FOR DETERMINATION OF HUMAN SUBJECTS RESEARCH

All research conducted by University of Alaska Anchorage faculty, staff, or students, which involves human subjects must be reviewed by the Institutional Review Board (IRB). To determine if your project involves human subjects or is research under UAA IRB definitions, complete this form and send it to the UAA Research Compliance Officer, simumaw@uaa.alaska.edu.

For help, contact the Office of Research Integrity & Compliance (ORIC): (907) 786-1099.

Consider your activity (research project, thesis, study, task, assignment) and the data (information) you, a member of your research team, or a collaborator, plan to collect, when responding to these questions.
Activity Examples: surveys, questionnaires, focus groups, interviews Š passive observation of public behavior (in physical or online environments, including social media) Š experiments using electronic equipment or gaming techniques Š the use of instruments or devices, including phones, to collect or monitor or influence behavior Š diet, nutrition studies, or taste tests Š physical or biomedical procedures, such as imaging, scanning, blood collection, anthropomorphic procedures Š studies examining individuals' responses to manipulation of their physical or online environment Š studies examining effectiveness of educational tools or curricula Š pilot studies and other preliminary studies Š any other activity that involves observation of, or interaction with, individuals to gather information for research.

Enter a response for each question, complete Section B on Page 2 and send to simumaw@uaa.alaska.edu	Yes/No Not sure
Is all of the data (information) being obtained about deceased people? (If No, skip the next question and go to RD1)	No
In addition to information about the deceased people, are you also collecting information from living persons about their recollections of the deceased people? (If No, stop here and go to RD 2)	
RD1) Does your project only involve existing data, information, documents, or samples that you will obtain from a publicly available source that does not require permission to access the data? (If Yes, stop here and go to RD2.)	No
Does a funding source (federal, state, or local), either directly (direct funder) or indirectly (secondary, or pass-through funder) require IRB review? (If Yes, stop here and go to RD3)	No
Is any of the data (information) being obtained about individuals who are, or could be, living now?	No
Is any of the data (information) being obtained, directly or indirectly, from living individuals?	Yes
Are you observing people, directly or indirectly, to collect your information?	No
Are you interacting (face-to-face, through telephone, electronic media or documents) with people?	Yes
Is the data collected by intervening (taking measurements, samples, images) with people, or observing an intervention carried out by another person?	No
Does the data/information you are collecting only center on things, quantities, or other questions about what item, process, or procedure is used? (If Yes, stop here and go to RD2)	Yes
Does the data/information you are collecting include the opinions, characteristics, or behavior of individuals?	
Does the data/information you are collecting include any information that could identify the individuals?	
Does the data/information you are using to recruit people for your project include any information that could identify the individual?	
During the process of collecting data, will you or any research team member, be able to identify the individuals?	
Will the data or information you are collecting examine, for example, the function of culture, expression of gender, or political views of members of the population in the study?	
Could the results of this evaluation be used to make a general conclusion about the data/information you will collect?	
Is this evaluation connected to individual or group outcomes?	
Could the results of this evaluation impact the future use of similar programs, services, or public policy?	
Can this evaluation affect the development or implementation of other programs of a similar nature?	

UAA UNIVERSITY of ALASKA ANCHORAGE

INSTITUTIONAL REVIEW BOARD
REQUEST FOR DETERMINATION OF HUMAN SUBJECTS RESEARCH

If you answered Not Sure for any question, briefly explain why you are uncertain. Briefly explain here.
RD**2** – Your work is most likely not human subject research and you do not need to complete the rest of the first section. Complete Section B and return the Request for IRB Determination form for a final confirmation.
RD**3** – Your work must be reviewed by the IRB. Go to IRBNet and complete a UAA IRB Proposal and all additional documents for IRB review.

Section B – Instructions, tab to each box and complete the information.

Name: Charlene Hill Today's Date: March 6, 2017

Affiliation with UAA (If this project will be used for class credit, complete the next two lines. If not, skip to Faculty/Staff):

Student Level: MSN Course Number: ND 696

Faculty Advisor: Lisa Jackson Department: School of Nursing

Faculty or Staff College or School: College of Health Department: School of Nursing

Project Title: Development of Evidence-Based Tools for Delivery of Mediation-Assisted Treatment in Opioid Dependency

Project Description: The purpose of this project is to develop and outpatient primary care evidence-based toolkit for medication assisted treatment (MAT) in opioid dependence for Alaska nurse practitioners. The project aims to increase provider knowledge of MAT modalities and to facilitate practice implementation with an overall goal of increasing the availability of trained and knowledgeable practitioners thereby increasing patient access to treatment for opioid dependency.
Population: Licensed family nurse practitioners within Alaska in the outpatient primary care setting.
Plan: Educational materials and MAT toolkit will be then be provided and time will be allotted for the healthcare providers to utilize the materials and implement MAT into clinical practice. A post-educational survey will be conducted 2 to 4 weeks after the educational presentation to assess provider knowledge and review provider recommendations for toolkit improvement.

For Office of Research Integrity & Compliance Use Only

Final Determination: HSR Not HSR

Statement of Findings: Focus on knowledge and recommendations of a product, not about the participants.

Appendix B

Project Implementation

You are invited to participate in the use of a medication-assisted treatment (MAT) toolkit for the treatment of opioid dependency. The toolkit is part of a practice improvement project for MAT in opioid dependency being conducted by Charlene Hill, BSN, RN as part of the requirements for a Master of Science in Nursing Science degree with the University of Alaska Anchorage.

Use of the MAT toolkit is voluntary; you will be asked to complete a brief follow-up survey regarding the toolkit. There are no risks associated with participation as the survey collects no identifying data of any respondent and all responses will be recorded anonymously. If you have any questions regarding participation in the survey or the practice improvement project, please contact Charlene Hill, BSN, RN at chill64@alaska.edu.

Your participation is voluntary and is greatly appreciated.

Current practice recommendations indicate that opioid dependency is a chronic illness and should be treated with a combination of psychosocial and pharmacotherapy (American Society of Addiction Medicine [ASAM], 2015; National Guideline Clearinghouse [NGC], 2011). There are three MAT medications approved by the Food and Drug Administration (FDA) for the treatment of opioid dependence.

1. Methadone
2. Buprenorphine
3. Naltrexone

Methadone and Buprenorphine require special certifications and special prescriptive authority, whereas any healthcare provider who can write prescriptions can prescribe naltrexone. Nurse practitioners who are willing to provide MAT with naltrexone can help increase patient access to treatment and positively impact the opioid epidemic.

Practice guidelines recommend treatment of opioid use disorders to include a combination of withdrawal management and psychosocial therapy or psychosocial therapy combined with methadone, buprenorphine, or naltrexone (ASAM, 2015). Aside from methadone

and buprenorphine, the alpha2-adrenergic agonist clonidine has also been used an effective treatment for opioid withdrawal management (Gowing, Farrell, Ali, & White, 2016). While a recent systematic review of the literature found that clonidine was more effective than placebo in the management of opioid withdrawal, clonidine is *not* an FDA approved medication for this indication (Gowing et al., 2016; ASAM, 2015). As such, withdrawal management will not be discussed in depth, as Nurse Practitioner prescriptive authority for MAT is limited to naltrexone. Caution should be taken to prevent severe withdrawal symptoms caused by naltrexone, and should only be used *after* detoxification and when the individual is no longer physically dependent on opioids (ASAM, 2015; SAMHSA, 2016a). It is also important to note that detoxification alone is not a recommended treatment for opioid dependency (ASAM, 2015).

The once-monthly injectable Naltrexone (Vivitrol) has been approved for both opioid and alcohol dependence; however, this project is specific to opioid dependency and therefore will not include alcohol treatment information. Upon request, the Alkermes Vivitrol pharmaceutical representative may provide further information regarding treatment of alcohol dependence and opioid detoxification protocols.

Appendix C

MAT Toolkit

The following information, referred to as the MAT toolkit, has been gathered and provided to facilitate MAT in your clinical practice.

The MAT toolkit includes:

- MAT of Opioid Use Disorder, Pocket Guide – a resource provided by Substance Abuse and Mental Health Services Administration (SAMHSA) with information on the three available MAT medications
- Medical Provider Checklist – screening tool to help decide if Vivitrol is appropriate for your patient
    - Patient must be free of all opioids for at least 7 days prior to Vivitrol administration
- Clinical Opiate Withdrawal Scale – tool to assess withdrawal symptoms, the need for inpatient detoxification, and to measure patient progress
- Patient Education Overview – patient information handout on Vivitrol
- Patient Counseling Tool – information to review with patients on Vivitrol at each encounter
- Medication Guide to Vivitrol
- Prescribing Information for Vivitrol
- Patient Injection Poster – Vivitrol injection visual aid
- Vivitrol Billing and Coverage Information and Resources – CPT and ICD-10 codes included
    - Providers may choose to purchase Vivitrol and bill patients insurance, send prescription to specialty pharmacy with delivery to the office or administration at the specialty pharmacy or send prescription to retail pharmacy for patient pick up with administration in office
    - TouchPoints Support Services – can assist providers and patients with prescriptions to specialty pharmacies and medication delivery, prior authorization support, co-pay assistance (self-pay or commercial insurance patients only), reimbursement coverage verification, and claims review
    - Providers may request a limited number of Vivitrol samples for immediate access in the clinic

Appendix D

Post-Implementation Survey

Thank you for participating in this practice improvement project for medication-assisted treatment (MAT) for opioid dependency. This final survey is intended to measure awareness and knowledge of MAT in opioid dependence and the overall satisfaction of the information provided to you.

There are no risks associated with participation as the survey collects no identifying data of any respondent and all responses will be recorded anonymously. By completing and submitting this survey, you are indicating your consent to participate in this practice improvement project. Your participation and feedback is invaluable and greatly appreciated.

---

1. What are the three MAT medications approved by the Food and Drug Administration (FDA) for the treatment of opioid dependence?
   Choose one:
   a. Methadone, naloxone, and buprenorphine
   b. Methadone, naltrexone, and buprenorphine
   c. Methadone, naltrexone, and butorphanol
   d. Methadone, nalbuphine, and buprenorphine
   e. Methadone, naltrexone, and bumetanide

2. Special certifications and prescriptive authority (aside from a DEA license) are required for all three MAT medications. *Choose one:*
   a. True
   b. False
   c. Unsure

3. For some opioid dependent patients, MAT is not necessary once they are past the detoxification phase and have been opioid-free for at least 7 to 10 days. *Choose one:*
   a. True
   b. False
   c. Unsure

4. Treatment for opioid dependence should be approached like other chronic diseases such as diabetes, asthma, and hypertension. *Choose one:*
   a. Agree
   b. Neither agree or disagree
   c. Disagree

5. How likely are you to provide medication-assisted treatment for opioid dependence after toolkit dissemination? *Check one:*
   _____ Very likely
   _____ Somewhat likely
   _____ Undecided
   _____ Somewhat unlikely
   _____ Very unlikely

6. Do you intend to use the MAT toolkit in future practice? *Check one:*
   _____ Definitely
   _____ Most likely
   _____ Maybe
   _____ Not likely
   _____ Definitely not

7. Is there any information you feel would be helpful to include in the toolkit?